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# Principles for Developing Innovative HIV Digital Health Interventions:

## The Case of Positive Health Check

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Digital health interventions use technologies such as mobile phones and tablets to influence health-related behaviors.[1] Widespread access and use of digital technologies have contributed to the increased adoption of digital health interventions. According to the Pew Research Center, 90% of American adults have a cell phone and 68% have a smartphone.[2] Cell phone ownership is similarly high across various demographic groups such as race/ethnicity, education levels, income, and community type.[2] Digital health technologies are being used for human immunodeficiency virus (HIV) prevention and treatment as well as for other health arenas such as cardiovascular disease, physical activity, and smoking cessation.[3–8] The adoption of digital health interventions is changing the intervention landscape and may impact intervention design, formation of project teams, and regulatory issues such as data security and patient privacy surrounding implementation of these interventions.

The convergence of technology and behavioral change interventions creates an exciting yet challenging opportunity. Digital interventions to support behavior change are becoming more ubiquitous and are developing at a rapid pace.[9,10] Subsequently, these technological advances are generating new types of data at a higher quantity than ever before.[9,10] As new technology-based behavioral change interventions are created, planning will be imperative to create timely and relevant interventions that can adapt and be updated as technologies evolve. To address these challenges and help speed digital intervention development to support people managing HIV and their clinical providers we share experiences and lessons learned. These are based on the development of Positive Health Check (PHC) and draw on

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the literature related to intervention development to provide principles to support research and practice.

PHC is a web-based tool that delivers tailored evidence-based prevention messages to HIV-positive patients through a series of brief interactive videos designed to simulate a conversation with an HIV primary care provider and is delivered via tablet to patients in HIV primary care clinics before regularly scheduled appointments. PHC aims to improve clinical outcomes including patients' improving antiretroviral therapy (ART) initiation and adherence, improving retention in care, reducing sexual risk, reducing mother-to-child transmission, and reducing risks associated with injection drug use. On the basis of responses to questions, each patient watches individually tailored videos on these topics, selects questions to ask their clinic doctor during their scheduled appointment and chooses behavioral tips to practice before their next clinic visit. A patient handout featuring this information is automatically printed and delivered to the patient. At the end of the intervention, patients can also opt to view supporting resource materials.

Recently, there have been a growing number of articles pertaining to digital health interventions with a domestic and international focus.[1,11,12] However, there is a gap in the literature on principles specific to the design, development, and implementation of HIV digital health interventions in the United States. In this paper, 5 key principles are presented that we identified as pivotal during the design, development, and implementation of PHC.

- Principle 1: a team science approach helps to address barriers to effective intervention development.
- Principle 2: interventions should be theory based and when possible, draw from other theory-based interventions that have evidence of efficacy or effectiveness.
- Principle 3: privacy and data security considerations need to be recognized at all stages of development and implementation.
- Principle 4: designing for engagement requires user input, testing, and revision.
- Principle 5: plan and design for adoption, scale, and sustainability.

According to the 2016 HIV Surveillance Report from the CDC, at the end of 2015 there were 973,846 persons living with diagnosed HIV in the United States.[13] In 2016, there were 39,782 HIV diagnoses.[13] PHC was developed in response to a need for interventions that are cost effective, can reach high-risk and hard-to-reach populations, and are designed from the onset to be taken to scale.[14] PHC was piloted in 4 primary care clinics in the United States to assess its perceived acceptability, appropriateness, and feasibility. These 5 principles have been refined during the PHC development process and pilot implementation and provide guidance for HIV researchers and clinicians as they develop future HIV digital health interventions.

## PRINCIPLE 1: A TEAM SCIENCE APPROACH HELPS TO ADDRESS BARRIERS TO EFFECTIVE INTERVENTION DEVELOPMENT

The first principle focuses on the importance of using a team science approach when conducting a digital health intervention. Designing, evaluating, and disseminating digital health interventions requires partnerships between information technology professionals, researchers, clinicians, participating institutions, and target users. A team science approach brings together researchers from multiple disciplines supporting engagement and collaboration to identify and solve complex problems.

Stokols et al[15,16] define the ecology of team science as the "complex web of intrapersonal, interpersonal, organizational, institutional, physical environmental, technologic, and other political and societal factors that influence the effectiveness of transdisciplinary collaboration in research, training, clinical, and public-policy settings." Multiuniversity research teams are a key example of the effectiveness of team science. Teams have produced higher impact and more frequently cited research than individual investigators.[17] However, not all teams are equally effective; 5 factors were identified that contribute to effectiveness of teams: (1) team member familiarity and social cohesiveness; (2) team size; (3) leadership traits and behaviors; (4) participatory goal setting and communication patterns; and (5) task and outcome interdependence.[16]

The literature suggests that increased familiarity among team members combined with greater social cohesiveness leads to increased productivity.[18,19] Optimal team size depends on a number of factors, and it is important to recognize the effects of size on coordination, time to reach decisions, and access to resources.[16] Leadership traits and behaviors that are important for enhanced success include the ability to generate and sustain trust, empower and set goals, offer a strong vision of success, and a bias towards risk taking and action.[20,21] Participatory goal setting offers benefits such as providing structure, connection, and stimulating communication and cooperation.[18] Similarly good communication encourages feelings of trust and cohesion.[22] The literature suggests balancing between individual tasks and rewards and team tasks and rewards to achieve maximum effectiveness.[21]

Our experience developing PHC supports the literature on team science and demonstrates its value added (Table 1) and suggests that researchers consider adopting a team science approach. For example, teams should start discussions early and continue throughout the intervention development process to ensure that team members have a shared understanding of development goals. Sufficient technological resources that enable communication and data sharing (eg, internet access, email, and phone lines) are important to support the team science approach. Our experience also suggests that researchers consider barriers such as bandwidth restrictions or team member availability early in the project so that they can be resolved quickly.

## PRINCIPLE 2: INTERVENTIONS SHOULD BE THEORY BASED AND WHEN POSSIBLE, DRAW FROM OTHER THEORY-BASED INTERVENTIONS THAT HAVE EVIDENCE OF EFFICACY OR EFFECTIVENESS

The second principle emphasizes the importance of using a theory-based approach when designing and implementing digital health interventions. Research shows that many technology-based interventions do not have a theoretical basis.[3,23] Theory is especially important for digital health interventions because they are complex and occur within a diverse system of patients, clinicians, and health care systems.[3,24] Data collected through digital health interventions needs to allow for continual testing and advancement of theories.[10] Catalani et al[3] conducted a systematic review of the literature on mHealth (mobile phones and other wireless technologies) for HIV treatment and prevention and found that only a few studies mentioned a theoretical basis or conceptual framework that guided their assumptions about why mHealth might facilitate or cause the intended change.

Theory-based strategies can enhance the impact, usage, and retention of digital health interventions. Strategies such as tailoring content and increasing motivation have come from important theories including Elaboration Likelihood Model and Self-determination Theory.[25] These theoretical perspectives predict that tailoring to make information more relevant, within digital interventions may increase the likelihood of patients' engagement with intervention content and subsequent behavior change. In addition, health behavior theory facilitates evaluation, allowing researchers to identify which intervention components are effective and why.[26]

As the prevalence of digital interventions continue to increase, it is important for researchers to recognize the need for integrating theory-based strategies into these interventions. Given the knowledge base from the literature and our experience integrating theoretical foundations for PHC (Table 1), theory is vital to informing development and continuous improvement of digital health interventions. It is especially important to identify what kind of digital interventions (eg, mobile apps, activity trackers, digital health care systems, custom-tailored web-videos, online social support, text messaging interventions etc.) may be potentially more effective compared with traditional nondigital behavior change interventions. Future interventions should be designed and modified with these differences in mind. In addition, future research should be conducted to identify constructs in behavioral theories that can help to explain the core components of digital health interventions that facilitate their effectiveness in practice.

## PRINCIPLE 3: PRIVACY AND DATA SECURITY CONSIDERATIONS NEED TO BE RECOGNIZED AT ALL STAGES OF DEVELOPMENT AND IMPLEMENTATION

The third principle stresses the importance of recognizing the ethical implications of digital health interventions including patient privacy and data security. Ethical issues surrounding the use of the Internet for behavioral interventions and research have been discussed since

the expansion of Internet access in the late 1990s. The use of tablets, mobile phones, and other technologies for digital health interventions introduce another layer of complexity for privacy and security.

The literature identified 6 legal and ethical issues that should be considered when developing digital health interventions: privacy, confidentiality, data validity, potential misuse of Internet interventions by professionals, equality of Internet access, and credentialing issues.[27] Numerous federal agencies have released guidelines and several states have enacted laws to protect the privacy and data of app and mobile app users.[28]

Bennett et al[29] suggest that security issues can be grouped into 3 categories. The first category, methodological, considers what kind of data are collected and stored, identifying the minimal level of data required for the project goals in order to protect privacy and confidentiality, minimizing breaches from the users and selecting the appropriate technology for a high level of security. The second category, technical, considers the security of the software application itself and the infrastructure used to develop the intervention. The last category, procedural, considers who has access to the data, intended uses of the data and procedures for handling potential security breaches.[29] These security and privacy issues need to be addressed from the start of the intervention development process.[23,29]

In keeping with guidance from the literature and what we learned about privacy and security from our PHC project experience (Table 1), we suggest that investigators carefully evaluate security issues in these methodological, technical, and procedural areas. Users need to know where their information is going, where it will be stored and allow users to decide who accesses certain types of information.

## PRINCIPLE 4: DESIGNING FOR ENGAGEMENT REQUIRES USER INPUT AND TESTING

The fourth principle focuses on enhancing engagement through user-centered design. The universality of digital technology has introduced a new means for the delivery of health care services and patient education. However, new forms of digital technology are continually available to consumers and constantly competing for their attention. Employing user-centered design to develop a digital health intervention is beneficial toward improving the end-user's experience, encouraging engagement and attentiveness toward the intervention, and facilitates widespread adoption.

Attfield et al[30] identified 8 characteristics associated with user engagement in digital interventions that aim to provide insight into both design approaches and evaluation measures. These include (1) focused attention; (2) positive affect; (3) esthetics; (4) endurability; (5) novelty; (6) richness and control; (7) reputation, trust, and expectation, and (8) user context. To develop an intervention that is engaging, end-user input and testing through user-centered design is key. In user-centered design, end-users influence the design throughout all stages of development and include not only the target user of the intervention but also the technology development team, the provider responsible for treating the target

user, and any third party payers if relevant.[1] The PHC experience with principle 4 is presented in Table 1.

Given the findings above, we strongly recommend the involvement and collaboration of end-users from the start of the design process. This may help to determine the end-user's individual needs and how to most effectively engage them. In addition, researchers should take an agile science approach and develop a timeline that allows for an iterative design and evaluation cycle.[9] Flexibility in the development process can help to allow for redesigning and editing the digital health intervention based on the end-users' experience, needs, and feedback.

## PRINCIPLE 5: PLAN AND DESIGN FOR ADOPTION, SCALE, AND SUSTAINABILITY

This principle addresses designing digital health interventions so they are easy to scale up and disseminate broadly, easy and affordable to adopt in low-resource settings, and easy to update. Digital interventions have many advantages over traditional intervention delivery channels. These advantages must be leveraged by designing digital health interventions in ways that use technology that can be accessed by a broad audience (both in terms of access to technology and the cost of adoption), and that allows for easy dissemination of updates as new knowledge and health information emerges and as technology changes. This improves both the ability to bring an intervention to scale as well as increases its sustainability so that intervention adopters do not have to continuously learn and adopt new interventions.

The Diffusion of Innovations theory provides 5 key characteristics of innovations, such as digital health interventions, that impact how likely they are to be adopted. These include (1) relative advantage, (2) compatibility, (3) complexity, (4) trial ability, and (5) observability.[31] Furthermore, in a systematic review, Gagnon et al[32] identified 9 key factors specific to mobile-health adoption, which include: (1) perceived usefulness and ease of use, (2) design and technical concerns, (3) cost, (4) time, (5) privacy, (6) security issues, (7) familiarity with the technology, (8) risk-benefit assessment, and (9) interaction with others (colleagues, patients, management).

As the PHC example for principle 5 demonstrates in Table 1, planning for scale and sustainability from the beginning will be beneficial for digital health interventions. It is important to design for individual and organizational end users in light of their barriers and facilitators to intervention adoption, focusing on behavioral and technology resources perspectives. Digital health inventions should not act as a barrier to workflow practices so it is important to identify the best way for the intervention to be delivered to the end user. Finally, researchers should try to consider the future of technology and attempt to develop in a way that will allow the intervention to be easily updated as technology changes.

## CONCLUSIONS

These 5 principles are not meant to be an exhaustive list of considerations for the development of digital health interventions but instead aim to provide an initial framework.

On the basis of the experience and lessons learned through the development of PHC, the principles were determined to be critical for developing digital health interventions. The principles should be tested and refined based on the development of future digital health interventions. Doing so will improve the efficiency of digital health interventions and spur the development and dissemination of effective interventions serving vulnerable populations.

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## REFERENCES

1. Pagoto S, Bennett GG. How behavioral science can advance digital health. Transl Behav Med. 2013;3:271–276. [PubMed: 24073178]
2. Pew Research Center. Cell phone and smartphone ownership demographics. Available at: www.pewinternet.org/data-trend/mobile/cell-phone-and-smartphone-ownership-demographics/. Accessed July 14, 2016.
3. Catalani C, Philbrick W, Fraser H, et al. mHealth for HIV treatment & prevention: a systematic review of the literature. Open AIDS J. 2013; 7:17–41. [PubMed: 24133558]
4. Noar SM, Willoughby JF. eHealth interventions for HIV prevention. AIDS Care. 2012;24:945–952. [PubMed: 22519523]
5. Consolvo S, Landay JA, McDonald DW. Designing for behavior change in everyday life. Computer. 2009;42:86–89.
6. Widmer RJ, Collins NM, Collins CS, et al. Digital health interventions for the prevention of cardiovascular disease: a systematic review and meta-analysis. Mayo Clin Proc. 2015;90:469–480. [PubMed: 25841251]
7. Ahsan GM, Addo ID, Ahamed SI, et al. Toward an mHealth intervention for smoking cessation. 2013 IEEE 37th annual computer software and applications conferences workshop. Japan; July 22–26, 2012; pp. 345–350.
8. Norman GJ, Zabinski MF, Adams MA, et al. A review of eHealth interventions for physical activity and dietary behavior change. Am J Prev Med. 2007;33:336–345. [PubMed: 17888860]
9. Patrick K, Hekler EB, Estrin D, et al. The pace of technologic change: implications for digital health behavior intervention research. Am J Prev Med. 2016;51:816–824. [PubMed: 27745681]
10. Michie S, Yardley L, West R, et al. Developing and evaluating digital interventions to promote behavior change in health and health care: recommendations resulting from an international workshop. J Med Internet Res. 2017;19:e232. [PubMed: 28663162]
11. Waugaman A From Principle to Practice: Implementing the Principles for Digital Development. Washington, DC: The Principles for Digital Development Working Group; 2016.
12. Yardley L, Morrison L, Bradbury K, et al. The person-based approach to intervention development: application to digital health-related behavior change interventions. J Med Internet Res. 2015;17:e30. [PubMed: 25639757]
13. Centers for Disease Control and Prevention. HIV Surveillance Report, 2016. 2016. Available at: www.cdc.gov/hiv/pdf/library/reports/surveillance/cdc-hiv-surveillance-report-2016-vol-28.pdf. Accessed April 2, 2018.
14. Centers for Disease Control and Prevention. High-impact HIV prevention: CDC's approach to reducing HIV infections in the United States. 2015. Available at: www.cdc.gov/hiv/policies/hip/hip.html. Accessed May 9, 2017.
15. Stokols D, Hall KL, Taylor BK, et al. The science of team science: overview of the field and introduction to the supplement. Am J Prev Med. 2008;35(suppl):S77–S89. [PubMed: 18619407]

16. Stokols D, Misra S, Moser RP, et al. The ecology of team science: understanding contextual influences on transdisciplinary collaboration. Am J Prev Med. 2008;35(suppl):S96–S115. [PubMed: 18619410]
17. Jones BF, Wuchty S, Uzzi B. Multi-university research teams: shifting impact, geography, and stratification in science. Science. 2008;322: 1259–1262. [PubMed: 18845711]
18. Guzzo RA, Dickson MW. Teams in organizations: recent research on performance and effectiveness. Annu Rev Psychol. 1996;47:307–338. [PubMed: 15012484]
19. Kerr NL, Tindale RS. Group performance and decision making. Annu Rev Psychol. 2004;55:623–655. [PubMed: 14744229]
20. Bennis W Organisation: the secrets of great groups. Leader to Leader. 1997;3:29–33.
21. Stewart GL. A meta-analytic review of relationships between team design features and team performance. J Manage. 2006;32:29–55.
22. Kayes AB, Kayes DC, Kolb DA. Experiential learning in teams. Simulation Gaming. 2005;36:330–354.
23. Wu YP, Steele RG, Connelly MA, et al. Commentary: pediatric eHealth interventions: common challenges during development, implementation, and dissemination. J Pediatr Psychol. 2014;39:612–623. [PubMed: 24816766]
24. Pingree S, Hawkins R, Baker T, et al. The value of theory for enhancing and understanding e-health interventions. Am J Prev Med. 2010;38:103–109. [PubMed: 20117565]
25. Morrison LG. Theory-based strategies for enhancing the impact and usage of digital health behaviour change interventions: a review. Digital Health. 2015. Doi:10.1177/2055207615595335.
26. Glanz K, Rimer BK, Viswanath K. Health Behavior and Health Education: Theory, Research, and Practice, 5th ed. San Francisco, CA: Jossey-Bass; 2015. Available at: www.wiley.com/WileyCDA/WileyTitle/productCd-1118628985.html. Accessed July 14, 2016.
27. Ritterband LM, Gonder-Frederick LA, Cox DJ, et al. Internet interventions: In review, in use, and into the future. Prof Psychol Res Pract. 2003;34:527–534.
28. Hughes PP, Goldstein MM. Privacy, security, and regulatory considerations as related to behavioral health information technology. Behavioral Healthcare and Technology: Using Science-based Innovations to Transform Practice. New York, NY: Oxford University Press; 2014:224–238.
29. Bennett K, Bennett AJ, Griffiths KM. Security considerations for e-mental health interventions. J Med Internet Res. 2010;12:e61. [PubMed: 21169173]
30. Attfield S, Kazai G, Lalmas M, et al. Towards a science of user engagement (position paper). 2011. Available at: http://ir.dcs.gla.ac.uk/~mounia/Papers/engagement.pdf. Accessed July 14, 2016.
31. Glanz K, Rimer BK. Theory at a Glance: A Guide for Health Promotion Practice. Washington, DC: National Cancer Institute; 2005.
32. Gagnon MP, Ngangue P, Payne-Gagnon J, et al. m-Health adoption by healthcare professionals: a systematic review. J Am Med Inform Assoc. 2016;23:212–220. [PubMed: 26078410]

**TABLE 1.**

Principles and PHC Intervention Examples

| Principles | PHC Example | Value Added |
|---|---|---|
| Principle 1: team science approach helps to address barriers to effective intervention development | The PHC development team involved PLWH, HIV prevention providers, researchers, communication scientists, IT development specialists, user interface/ user experience (UI/UX) and graphics and web design experts | An intervention with visual design, programing, and content that draws on best practices from multiple fields, culminating in a responsive and innovative end-product |
| Principle 2: interventions should be theory based and, when possible, draw from other theory-based interventions that have evidence of efficacy or effectiveness | PHC's approach and messaging is grounded in the theoretical underpinnings of the Information-BehaviorMotivation model, Motivational Interviewing, and the Transtheoretical Model, and draws on previously proven effective video-based interventions | Increased likelihood of behavior change and improved patient health outcomes for PLWH |
| Principle 3: privacy and data security considerations need to be recognized at all stages of development and implementation | PHC does not collect any personal identifying information and only collects data necessary for evaluating the implementation process. Data are transmitted directly to a secure server, as opposed to being stored in the tool. In addition, patients are provided with headphones and a privacy screen when engaging with the intervention | HIV patients feel more comfortable answering questions honestly and clinics are more likely to adopt the intervention knowing that patients' data are secure |
| Principle 4: designing for engagement requires user input and testing | Technical consultants comprising end-user groups (HIV providers and patients) provided feedback on all aspects of the intervention, from design considerations to implementation protocols, which was used to refine the tool's design, content, and integration into the clinic | Development of a user-friendly intervention that was well received by HIV clinic patients and providers during the pilot implementation |
| Principle 5: plan and design for adoption, scale, and sustainability | PHC was developed using dynamic web design technology, requires minimal bandwidth, and is compatible for use on multiple types of devices, including tablets, laptops, and desktops | An intervention that can be easily updated and is scalable to reach high-risk, rural, and lowliteracy populations in low-resource settings |

HIV indicates human immunodeficiency virus; IT, information technology; PHC, Positive Health Check; PLWH, people living with HIV.